K070581

JUL 13 2007

Section 11 – Traditional 510(k): Device Modification -Summary

This Traditional 510(k) Device Modification is to provide substantial equivalence for Advanced Medical Solutions Limited's Silver Alginate II Dressing, which is substantially equivalent to currently marketed devices intended for wound care. This product is already legally marketed as Silver Alginate II Dressing (unmodified device) and was previously cleared under 510(k) numbers **K041316/K063173**. Both submissions have been made by Advanced Medical Solutions Limited.

Submitted by:-	Advanced Medical Solutions Limited Road Three Winsford Industrial Estate Winsford Cheshire CW7 3PD United Kingdom
Contact:-	Mrs Claire Ryan Regulatory Affairs Manager
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Email:-	Claire.ryan@admedsol.com

Date prepared:-	2nd February 2007
Classification:-	There is currently no classification for wound and burn dressings.
Common Name:-	Silver Alginate II Dressing
Trade Names:-	Maxsorb Extra Ag Seasorb Ag Invacare Silver Alginate Dressing
Predicate devices:-	K041316 Silver Alginate II Dressing manufactured by Advanced Medical Solutions K013814 Aquacel Ag with hydrofibre manufactured by ConVatec, A division of E.R Squibb and Sons LLC. K002896 Acticoat® manufactured by Smith & Nephew Limited

Directions for use: - Silver Alginate II Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds such as:

- Post-operative wounds
- Trauma wounds (dermal lesions, trauma injuries or incisions)
- Leg Ulcers
- Pressures Ulcers
- Diabetic Ulcers
- Graft and donor sites
- Post-operative surgical wounds
- 1st and 2nd degree burns
- Partial and Full Thickness wounds

Silver Alginate II Dressing is indicated for external use only

Device Description: - Silver Alginate II Dressing is a sterile, non woven pad composed of a high G (guluronic acid) calcium alginate, carboxymethylcellulose (CMC) and ionic silver complex (Silver Sodium Hydrogen Zirconium Phosphate), which releases silver ions in the presence of wound fluid. As wound fluid is absorbed the alginate forms a gel, which assists in maintaining a moist environment for optimal wound healing, and allows intact removal.

The silver ions protect the dressing from a broad spectrum of microorganisms over a period of up to twenty-one (21) days, based on *in-vitro* testing. . Odour reduction results from the antibacterial effect in the dressing.

Silver Alginate II Dressing is an effective barrier to bacterial penetration.

Silver Alginate II Dressing protects the wound and aids autolytic debridement therefore facilitating wound healing.

	The dressing has an off-white appearance and is available in various sizes (5cm x 5cm, 10cm x 10cm, 15cm x 15cm, 10cm x 20cm, 20cm x 30cm flat dressings; 2.7cm x 30cm and 3cm x 44cm flat rope dressings; and 30cm x 2g rope dressings). The flat rope dressings are packaged in pouches and the flat rope and rope dressings are packaged in a blister pack.
Testing:-	The biocompatibility of Advanced Medical Solutions Limited Silver Alginate II Dressing has been demonstrated to be in compliance with the requirements of BS EN ISO 10993-1. Sterilisation validation has been performed in compliance with harmonised standards.
Statement of:- Substantial Equivalence	The Silver Alginate II Dressing is a non-woven calcium alginate dressing which is substantially equivalent in construction and/or performance to both Anticoat® Calcium Alginate Dressing and Aquacel Ag absorbent antimicrobial wound dressing predicate devices. Comparable absorbency, silver release profile and antimicrobial activity have been demonstrated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2007

Advanced Medical Solutions, Ltd
% Ms. Claire Ryan
Regulatory Affairs Manager
Road Three, Winsford Industrial Estate
Winsford, Cheshire, CW7 3PD
United Kingdom

Re: K070581
Trade/Device Name: Silver Alginate II Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 20, 2007
Received: June 22, 2007

Dear Ms. Ryan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Peter D. Rumm MD

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DEP D. Lee for
7/13/07

Enclosure

Indications for Use

510(k) Number (if known): **K070581**

Device Name: **Silver Alginate II Dressing**

Indications for Use:

Silver Alginate II Dressing is indicated for the management of moderate to heavily exuding partial to full thickness wounds, such as:

- Post-operative wounds
- Trauma wounds (dermal lesions, trauma injuries or incisions)
- Leg Ulcers
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- Diabetic Ulcers
- Graft and donor sites
- Post-operative surgical wounds
- 1st and 2nd degree burns
- Partial and Full Thickness wounds

Silver Alginate II Dressing is indicated for external use only

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070581